MAY 1 0 2002

K020617

510(k) Summary

Name/Address of Submitter: NSI, Inc.
10565 Lee Highway, Suite 100
Fairfax, VA 22030

Contact Person: Greta M. Hols Phone: (703) 278-3953 Fax: (703) 278-3954

Date Summary Prepared: February 22, 2002

Device Name: Endosseous Implant and Accessories

Trade Name: NSI Hexed and Non-Hexed Implant System

Purpose: **The purpose of this supplemental 510(k) is to include additional implants and accessories in the NSI Hexed and Non-Hexed Endosseous Implant System (K003620) that did not fall within the size range and design shapes identified in our original 510(k) submission for our system.**

Predicate Devices: K003620 NSI Hexed and Non-Hexed Implant System
K951111 Restore Self-Tapping Dental Implant System
K944068 Restore Self-Tapping Dental Implant System
K874590 Innovative Implants and Cover Screws
K894594 Bonefit Hollow Screw Implants
K925773 Branemark System Gold Cylinders and Screws
K002475 Replace TPS Coated Implant
K925769 Branemark Systems Abutments Complete
K925777 Branemark System Etheticone Abutment Complete

Device Description and Intended Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the NSI Hexed and Non-Hexed Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Conclusions Drawn: The NSI Hexed and Non-Hexed Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2002

Ms. Greta M. Hols
NSI
10565 Lee Highway, Suite 100
Fairfax, Virginia 22030

Re: K020617
Trade/Device Name: NSI Hexed and Non-Hexed Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: February 22, 2002
Received: February 25, 2002

Dear Ms. Hols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020617

Indication for Use

510(k) Number:

Device Name: Endosseous Dental Implant System

Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the-counter Use _____.
(Per 21 CFR801.109)

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020617